

RegulatedManufacturedItem FHIR Resource Proposal

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Draft resource in build:
[Relationship to other resources](#)

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[BR&R](#)

[Committee Approval Date](#)[:\[edit | edit source\]](#)

6th May 2019

[Contributing or Reviewing Work Groups](#)[\[edit | edit source\]](#)

- Pharmacy
- Orders and Observations

[FHIR Resource Development Project Insight ID](#)[\[edit | edit source\]](#)

1367

[Scope of coverage](#)[\[edit | edit source\]](#)

To support the content of the ISO 11615 IDMP Medicinal Product standard and other domain areas with similar requirements. 11615 covers detailed definition of products, their submissions to regulators, authorization activities, ingredients, packaging, accompanying devices, clinical particulars etc. Not all of those are expected to be covered in this single resource.

[RIM scope](#)[\[edit | edit source\]](#)

Similar in scope to the product parts of CPM. Entity: Material (EntityClass="MAT")

[Resource appropriateness](#)[\[edit | edit source\]](#)

There is an outstanding requirement to support the standardised exchange of detailed "Product" data, for regulatory and other use cases.

This resource does not intend to clash with the existing Medication resource, but complements it with an extra level of detail. It is seen as a sibling rather than a parent or a "superclass" to be profiled.

(The superclass option has widely discussed and rejected, since this would mean the Medication resource - much more commonly used - would become more complicated, being a very small profile of a very large model. We don't want to introduce such confusing complexity in that space - which is largely separate.)

This resource has been designed in close consultation with Pharmacy WG, and in conjunction with the MedicationKnowledge resource

RegulatedManufacturedItem is intended to add an extra level of product specification detail, such as is typically used by regulators, and only indirectly used during normal medication related work flows (e.g. for look-ups of unfamiliar products).

Drug manufacturers currently submit this data electronically to regulators, when products are registered or altered, or marketing situations change.

Expected implementations[[edit](#) | [edit source](#)]

EMA and European drug manufacturers, who have a requirement to submit to EMA (and already do so in a proprietary format). They are required to move to IDMP, and this is a good opportunity to use a standards-based FHIR solution.

FDA for drug submission (currently using SPL, which is not likely to change in the near term, but have expressed an interest in FHIR).

FDA for Pharmaceutical Quality (HL7 PSS approved, based on this resource, June 2019),

Content sources[[edit](#) | [edit source](#)]

The core basis for the resource is the information in ISO 11615 Medicinal Products standard, which is in turn partly based on the existing implementations in the EU and US. A large amount of actual data exists in the EMA EU XEVMPD data base (and XEVPRM XML messages). Example FHIR data for several full product data sheets exists based on draft resources.

Also, information gained from early stage implementation of these resources at EMA (2018, 2019), and from many many received to EMA about the draft API specification from the European medicines regulatory network (<https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network>).

Also from FDA requirements (for PQ/CMC) and other workgroup review (BR&R, Pharmacy) and their comments.

Example Scenarios[[edit](#) | [edit source](#)]

Pharma companies submit details of new products to regulators. Updates are made when necessary e.g. clinical particulars change (a new contra-indication), a new marketing authorization exists etc.

Pharmacies and prescribers can view and download this information for reference and integration with their systems.

Specific use cases include:

Submission of products from drug companies and NCAs (National Competent Authorities - the national regulators) to regional regulators. This is already implemented in Europe (by EMA and EU-wide stakeholders) with an earlier non-HL7 format (XEVPRM/XEVMPD). That scenario is currently being re-implemented, using this resource, as part of the EU wide SPOR project.

Drug Manufacturing Quality information (aka PQ/CMC, Pharmaceutical Quality), as used by the FDA in the US. Specific plans to use this resource for that project.

Resource Relationships[[edit](#) | [edit source](#)]

See diagram below.

Some notable resource references: Reference to Organization, for the manufacturer, regulator and other establishments. Reference to DocumentReference, for the regulatory submission documentation. Reference to directly supporting resources such as RegulatedPackagedProduct. Incoming reference from resource RegulatedAuthorization. Indirect reference to DeviceDefinition, via the other proposed resources (DeviceDefinition was created with O&O with input from this IDMP project and includes our all of our device requirements). Indirect reference to proposed SubstanceSpecification resource to describe ingredients in detail.

RegulatedManufacturedItem and Medication[[edit](#) | [edit source](#)]

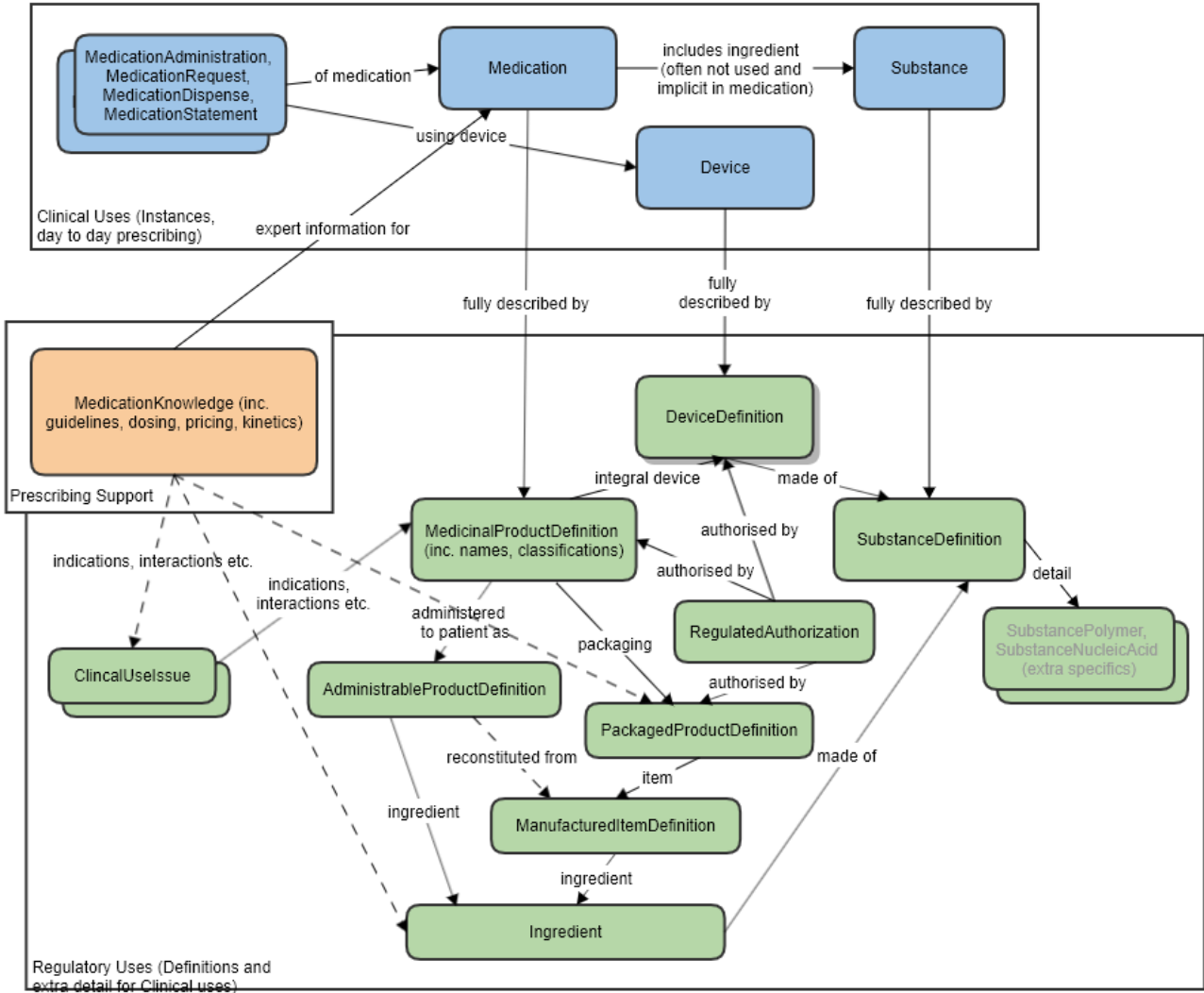
This resource is intended to complement the Medication resource, which is focused on what is commonly needed for medical/clinical use cases. RegulatedManufacturedItem adds information needed for regulatory use cases, of which there is little overlap to day to day prescribing.

Most aspects of RegulatedManufacturedItem are not present in Medication at all, and are not current candidates for inclusion in the prescribe/dispense /administer workflow.

RegulatedManufacturedItem and MedicationKnowledge[[edit](#) | [edit source](#)]

Also refer to the logical model which was used to clarify the resource relationships, at the request of FMG, in the preparation of this proposal (linked to the approved MedicationKnowledge proposal page): [MedicationKnowledge_FHIR_Resource_Proposal](#)

High level relationships of the main prescribing resources and the regulatory strata below:



Timelines[[edit](#) | [edit source](#)]

Draft content is modelled in the FHIR build (<http://build.fhir.org/regulatedmedicinalproduct.html>), with outline supporting documentation. Completion planned Q4 2019.

gForge Users[[edit](#) | [edit source](#)]

riksmithies

When Resource Proposal Is Complete[[edit](#) | [edit source](#)]

When you have completed your proposal, please send an email to FMGcontact@HL7.org

FMG Notes